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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,978	10/27/2003	Jacqueline C. Timans	DX0904KB1	4528
28008	7590	03/02/2006	EXAMINER	
DNAX RESEARCH, INC. LEGAL DEPARTMENT 901 CALIFORNIA AVENUE PALO ALTO, CA 94304			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/694,978

Applicant(s)

TIMANS, JACQUELINE C.

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) 28-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25, 27 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-20 have been canceled previously. Amended claims 21-25, 27 (1/27/2006) and new claim 34 (1/27/2006) are under consideration by the Examiner. Claims 28-33 have been withdrawn from consideration (10/27/05) by the Examiner.
2. Receipt of applicant's arguments filed on 5/27/2005 is acknowledged.
3. The following previous objections and rejections are withdrawn in light of applicants amendments filed on 1/27/2006:
 - (i) the objection to the title of the invention and to typographical errors in the specification;
 - (ii) the rejection of claims 21-24 under 35 USC 101 as being directed to non-statutory subject matter;
 - (iii) the rejection of claims 21-27 under 35 USC 101 and 35 USC 112, first paragraph for lack of a credible, specific or substantial utility; and
 - (iv). The rejection of claims 22-27 under 35 USC 112, second paragraph
4. Applicant's arguments filed on 1/27/2006 have been fully considered and were persuasive in part. The issues remaining are restated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 102(e)

6. Claims 21-23, 25, 27, 34 are rejected under 35 U.S.C. 102(e) as being anticipated by ~~the~~ Yang Pan (US Patent No. 6,117,654).

This rejection is maintained for reasons of record set forth at pages 9-10 of the previous Office action (10/27/2005).

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Applicants argue that since the claimed antibodies or antigen-binding fragments specifically bind a polypeptide consisting of SEQ ID NO:2 or 4, they would not bind the TANGO-77 protein, which is different and unrelated from the polypeptide consisting of SEQ ID NO:2 or 4. Furthermore, Applicants argue that the present specification teaches how to assay for specifically binding antibodies on page 62, line 12 through page 64, line 9, of the specification and that a person of ordinary skill in the antibody art would not consider the antibody that binds both SEQ ID NO:2 or 4 and TANGO-77 as specifically binding a polypeptide of SEQ ID NO:2 or 4. However, contrary to Applicants' arguments, because the TANGO-77 polypeptide sequence of the reference shares a sequence of over 50 amino acids which are 100% identical to the claimed amino acid sequence of SEQ ID NO:2, the antibody of the reference would be expected by one of ordinary skill in the art to bind to the polypeptide of SEQ ID NO:2.

Furthermore, Applicants have not taught which epitopes are recognized by the claimed antibodies. Epitopes generally are 5-10 amino acids in length. There is a contiguous stretch of 50 amino acids between the prior art protein and Applicants' SEQ ID NO:2. Given the size of the prior art protein and Applicants' SEQ ID NO:2 and the high degree of similarity and overlap between the two sequences, it is reasonable to conclude that an antibody to the TANGO-77 protein would specifically bind to Applicants' SEQ ID NO:2 because there are multiple epitopes in common between the TANGO-77 polypeptide and Applicants' SEQ ID NO:2. A comparison of the two sequences indicates that a vast majority of potential epitopes are the same between TANGO-77 and Applicants' SEQ ID NO:2.

Also, Applicants argue that page 62, lines 13-19 discloses that:

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“An IL-1 ζ polypeptide that specifically binds to or that is specifically immunoreactive with an antibody, e.g., such as a polyclonal antibody, generated against a defined immunogen, e.g., such as an immunogen consisting of an amino acid sequence of SEQ ID NO: 2 or fragments thereof or a polypeptide generated from the nucleic acid of SEQ ID NO:1 is typically determined in an immunoassay.”

However, contrary to Applicants arguments, the recitation of “e.g.” in the specification indicates that there is no precise definition of the term “specifically” in the instant specification and the antibodies disclosed are exemplary. Further, the specification, page 62, line 17, explicitly discloses that antibodies can be generated to fragments of SEQ ID NO:2, which encompasses the antibody of the prior art against the 50 amino acid stretch of amino acids in common between TANGO-77 and the instant polypeptide of SEQ ID NO:2. Applicants have not shown by a side-by-side comparison that an antibody to TANGO-77 would not bind specifically to SEQ ID NO:2.

Therefore, the antibody of the reference anticipates instant claims 21-23, 25, 27, 34.

Claim Rejections - 35 USC § 103

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang Pan (US Patent No. 6,117,654) in view of the Stratagene catalog (1988, page 39).

This rejection is maintained for reasons of record set forth at pages 10-11 of the previous Office action (10/27/2005).

Applicants argue that the ‘654 patent fails to anticipate the antibodies of the present invention and that the Stratagene catalog fails to cure the deficiencies of the ‘654 patent.

However, contrary to Applicants’ arguments, for the reasons discussed above in paragraph 6, the

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'654 patent in view of the Stratagene catalog which teaches combining reagents to form a kit renders obvious the limitations of claim 24.

Conclusion

No claim is allowed.

Claims 21-25, 27 and 34 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Prema Mertz Ph.D., J.D.

Primary Examiner

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February 15, 2006